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K140321

APR 17 2014

Special 510(k) Summary for the Unitary Pediatric Better-Bladder™ (BB14-72)
Preparation Date: 2/5/14

510(k) Owner/Contact Person Information:

Yehuda Tamari
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21 Singworth St.
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Device Information:

Trade Name: Unitary Pediatric Better-Bladder™
Common Name: in-line venous reservoir
Product Class: DTN (Reservoir, blood, cardiopulmonary bypass)

Description of the Device:

The Better-Bladder™ (BB) is a length of standard perfusion tubing, a portion of which has been processed to form a sausage shaped balloon with a thin wall that is then sealed within a clear, rigid housing. This device can be used as an inline blood reservoir during extracorporeal circulation. It can also be used to monitor the blood pressure noninvasively: because the pressure of blood flowing inside the tubing is transmitted across the thin wall to the housing chamber, this pressure can be monitored via a pressure monitoring line to a pressure sensor. The BB thereby serves as a pressure transducer protector, isolating the blood from the pressure sensor and allowing noninvasive pressure measurements, which in turn can be used as input signals to control the pump speed.

Equivalent Device:

Trade Name: Better-Bladder™
510(k) number: K981284 and K964337

Indication for Use:

The better-bladder is a device that isolates pressure transducers from blood contact when measurements of blood pressure in extracorporeal circuits are made during short and long term procedures. The pressure signal can be used to control pump speed. It is also used as an inline reservoir to provide compliance in the circuit during short and long term procedures.

Intended Use:

The BB14-72 has two intended uses:

1. To isolate pressure transducers from blood contact when measurements of blood pressure in extracorporeal circuits. The pressure signal can be used to control pump speed for routine bypass procedures.
2. As an inline blood reservoir to provide compliance in the extracorporeal circuits.

These intended uses are identical to the predicate device, the Better-Bladder™ (BB14, BBB38, and BBB38-72). The predicate devices include extracorporeal membrane oxygenation (ECMO) procedures as an intended use.

Technological Characteristics

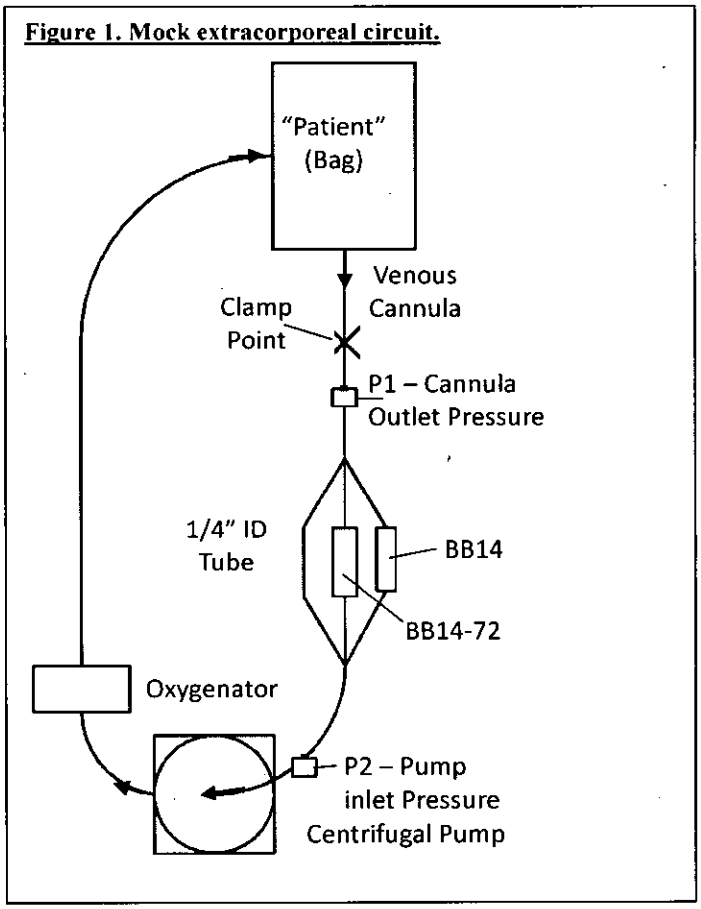
The BB14-72 has the same technical characteristics as the predicate device, the Better-Bladder™ (BB14, BBB38, and BBB38-72). See the following table:

Characteristic	BB14-72	Predicate Device
Design	Balloon section in a length of perfusion tubing	Balloon section in a length of perfusion tubing
Material	Balloon/tube: PVC Housing: PETG	Balloon/tube: PVC Housing: PETG
Energy source	None	None
Maximum flow	1.5 LPM	1.5 LPM

Performance Data

The BB14-72 was tested against the predicate device (BB14) and a length of ¼" standard perfusion tubing to compare the negative pressure spike due to a sudden obstruction of the venous line. This occurs when the pump is attempting to pump more than that available from the patient. The tests were conducted in a mock extracorporeal circuit, see Fig. 1. The pressure was measured at the P1 – Cannula Output Pressure point in Fig. 1. The flow in the circuit was either 500 mL/min or 1,500 mL/min. The venous line was clamped at the Clamp Point in Fig. 1, and the record pressure spikes are summarized in Fig 2.

Figure 1. Mock extracorporeal circuit.



From this performance data, we can conclude that the BB14-72 offers more compliance than the predicate device. The negative pressure spike for the BB14-72 was lower than that for the predicate device, and the time it took for the pressure to reach a steady state was longer with the BB14-72 than the predicate device. The lower pressure spike corresponds to a lower pressure that would be exerted a the venous cannula, and the longer time to reach steady state pressure allows more time for a pump flow controller to respond to the obstruction in the venous line. Thus, the safety of the BB14-72 is substantially equivalent to, and performs as safely and effectively or safer and more effectively as the predicate device.

Figure 2b. The negative pressure spike due to a sudden obstruction of the venous line (1,500 mL/min flow).

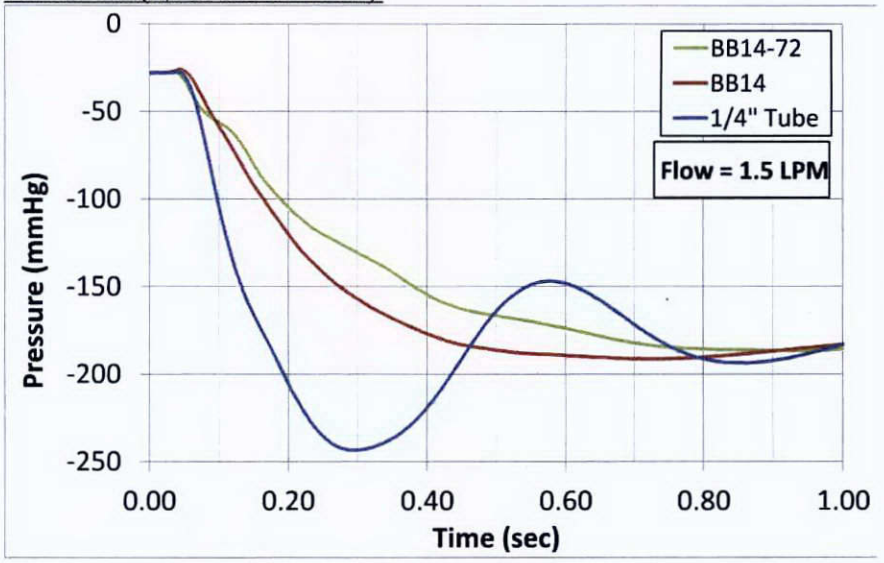
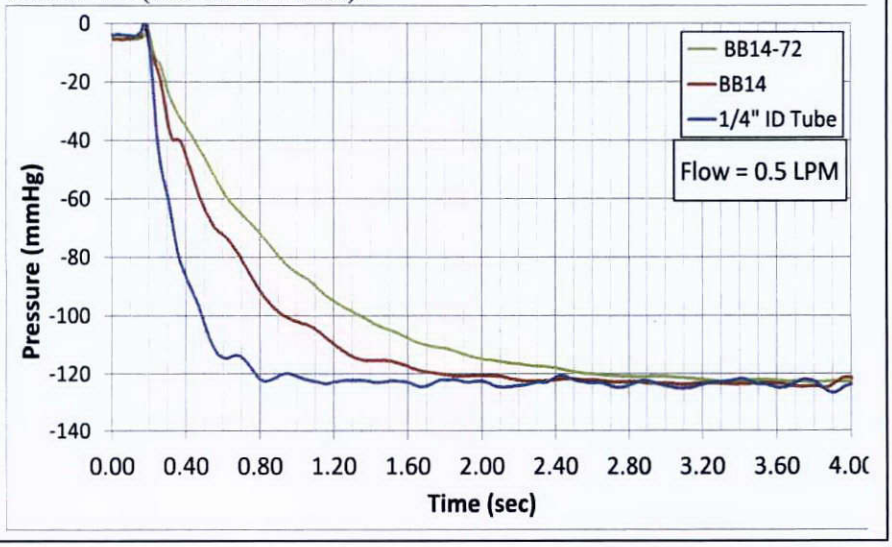


Figure 2a. The negative pressure spike due to a sudden obstruction of the venous line (500 mL/min flow).



Conclusion

The BB14-72 is substantially equivalent to the predicate device in design, Intended Use, Technological Characteristics, and Performance Characteristics. The materials of the BB14-72 are identical to those of the predicate device, as well as the manufacturer and sterilizer. The method of manufacture is also the same for both the BB14-72 and the predicate device. The BB14-72 protects against large negative pressure spikes as well or better than the predicate device, and it provides more time for a pump flow controller to respond than the predicate device, indicating that the BB14-72 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 17, 2014

Circulatory Technology, Inc.
Yehuda Tamari
President
21 Singworth St.
Oyster Bay, New York 11771

Re: K140321
Trade/Device Name: Initary better bladder-pediatric
Regulation Number: 21 CFR 870.4400
Regulation Name: Better-Bladder
Regulatory Class: Class II
Product Code: DTN,
Dated: February 5, 2014
Received: February 18, 2014

Dear Yehuda Tamari,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140321

Device Name
The Better-Bladder (BB14-72)

Indications for Use *(Describe)*

The Better-Bladder™ is a device that isolates pressure transducers from blood contact when measurements of blood pressure in extracorporeal circuits are made during short and long term procedures. The pressure signal can be used to control pump speed. It is also used as an inline reservoir to provide compliance in the circuit during short and long term procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Bram D. Zuckerman -S
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